Applicant : Arne H. Deggerdal et al. : Attorney's Docket No.: 08269-Serial No. : 08/849,686 003001 / 42.61695/006.hd

Serial No.: 08/849,686 Filed: August 21, 1997

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REMARKS

Claims 1, 5-17, 19-25, and 27-34 are pending and under examination. Applicants thank the Examiner and his supervisor for granting telephonic interviews with the undersigned on each of January 12, 13 and 14, 2004. During the first two discussions, the status of the case was briefly discussed. The third interview is summarized below.

The Office action rejected all of the pending claims as either anticipated by or obvious over Hawkins, U.S. Patent No. 5,898,071. Applicants point out that, as amended in the continued prosecution application filed August 16, 2002, all of the pending method claims are limited to methods of isolating genomic DNA (or, in some cases, RNA and genomic DNA) from a sample. The Response filed with that CPA on August 16, 2002, explains why this limitation distinguishes over the methods disclosed in Hawkins. The outstanding Office action recognizes that the present claims are drawn to a method of isolating genomic DNA from a sample (see, e.g., the top line of page 3 and the top line of page 4 of the Office action), but did not address, much less refute, applicants' explanation of why the limitation distinguishes over this reference. Applicants are grateful for the further clarification of the Examiner's position on this point in the interview of January 14, 2004, with the undersigned. According to the Examiner, Hawkins did refer to genomic DNA at col.4, lines 59-61. Although the Examiner acknowledged in the interview that this reference to genomic DNA did not say it was the final product to be isolated, the Examiner opined that the passage shows that genomic DNA nevertheless was separated from other constituents of the sample, thereby anticipating claims 1, 5-8, 10-14, 17, 24, 25, 27 and 30-34 and rendering claims 1, 5-17, 19-25 and 27-34 obvious. The Examiner also noted in the interview that the method claims recite a method "comprising" certain steps, and thus can include steps not explicitly recited in the claims. The Examiner invited applicants to file a response addressing these two points.

First, applicants note that the reference to genomic DNA at col.4, lines 59-61, does not indicate that the genomic DNA is ever bound to a solid support, much less in the presence of detergent and absence of a chaotropic agent as required by all of the present method claims. Hawkins mentions genomic DNA as a component of the host cells from which the "exogenous

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or foreign DNA" is to be isolated. Hawkins makes it clear that, following lysis of the cells, the genomic DNA is removed "by chemical treatment or centrifugation of the lysate, thereby leaving a solution containing plasmid DNA." (col.4, lines 42-47) It is only after that removal of genomic DNA that Hawkins introduces magnetic microparticles into the lysate. This makes sense, of course, if one's purpose is (like Hawkins') to isolate the "foreign" DNA (e.g., plasmid DNA) by binding to the microparticles. Thus, Hawkins never teaches that one should bind genomic DNA to his magnetic microparticles. Indeed, he teaches how to avoid that outcome, by first clearing the lysate of genomic DNA.

The kit claims (claims 16, 17, 27, 29, and 30) are drawn to kits for isolating genomic DNA (or RNA <u>and</u> genomic DNA). The required elements of the kit of claim 27 include "instructions for isolating genomic DNA according to the method of claim 1", while kit claim 30 requires inclusion of "instructions for isolating RNA and genomic DNA according to the method of claim 28." The other kit claims include other limitations not taught by Hawkins, including use of <u>superparamagnetic polystyrene beads</u> and/or oligo dT beads.

The second point raised by the Examiner during the telephonic interview addressed applicants' arguments in the August 16, 2002, response concerning the simplicity of the presently claimed methods in comparison with those of Hawkins. Applicants agree with the Examiner that the present claims use open language and so encompass methods that incorporate additional steps. The arguments previously presented by applicants were intended simply to highlight one of the great advantages of the present methods over those of Hawkins. Hawkins did not give any reason to expect one could isolate genomic DNA by a method or kit such as presently claimed. The fact that it can be done so simply is entirely unexpected in view of the prior art. As the Examiner is aware, unexpected results are cogent evidence of nonobviousness and must be taken into account when determining patentability over the art. Because Hawkins does not teach the presently claimed kits and methods, nor render them obvious, withdrawal of the rejections over this reference is requested.

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Enclosed is a \$950.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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